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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/813,950	03/03/97	ASSMUS M	583-252-0-FW

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EXAMINER	
SELLERS, R	
ART UNIT	**PAPER NUMBER**
1501	12

DATE MAILED: 09/02/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/813,950	Applicant(s) Assmus et al.
	Examiner Robert Sellers	Group Art Unit 1501

☒ Responsive to communication(s) filed on *Mar 3, 1997*

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1, 3, 5, 7, 9, 11, 13, 15, and 17-24* is/are pending in the application.

Of the above, claim(s) *1, 3, 5, 7, 9, 11, 13, and 15* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *17-24* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1, 3, 5, 7, 9, 11, 13, 15, and 17-24* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Serial Number: 08/813,950

Art Unit: 1501

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3, 5, 7, 9, 11, 13 and 15, drawn to a method for coating and binding a medicinal composition, classified in class 427, subclass 398.5.

II. Claims 17-24, drawn to a medicinal composition, classified in class 424, subclass 482.

The inventions are distinct, each from the other because:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process such as pressing the medicinal composition and sheathing with a liquid coating agent.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: The thermoplastic acrylic plastics A such as the aminoalkyl(amide) or quaternary ammonium-functional acrylic copolymers of claim 7.

Serial Number: 08/813,950

Art Unit: 1501

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 3, 5, 9, 11, 13, 15 and 17-24 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Samuel H. Blech on August 27, 1997, a provisional election was made with traverse to prosecute the invention of Group I and the constructive election of the aminoalkyl(amide) or quaternary ammonium-functional acrylic copolymers of claim 7, claims 17-24.

Affirmation of this election must be made by applicant in responding to this Office action. Claims 1, 3, 5, 7, 9, 11, 13 and 15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 17-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

There is no support for the application of the thermoplastic coating and binding agent as a hot-melt liquid to the oral or dermal medicinal composition, followed by cooling to solidify the thermoplastic coating and binding agent. The specification on page 1, line 16 to page 2, line 2, provides a general description of the preparation or sheathing of medicinal forms from a melt-liquid state possessing the capabilities of the thermoplastic and binding agents to be meltable and mixable in a solid state by cooling, and to solidify from the melt. Page 15, line 24 to page 16, line 12 describes the melt mixing, cooling, solidification and comminution of the thermoplastic coating and binding agent prior to the introduction of the oral or dermal medicinal composition. Page 17, lines 22-26 and page 21, Example 5 discloses the blending of a pharmaceutical active substance into the hot melt.

Accordingly, there is no revelation substantiating the claimed coating of the medicinal composition with a hot-melt liquid of the thermoplastic coating and binding agent since the specification merely describes the preparation of a powdered or granulated thermoplastic coating or binding agent prior to combination with the medicinal composition, or the blending of a pharmaceutical active substance into the hot melt without any indication of any subsequent processing of the mixture. There is no explanation as to whether the pharmaceutical active substance is a component in the thermoplastic coating or binding agent or is part of the medicinal composition to be coated.

The 35 U.S.C. 102(b) rejection over Moest is overcome by the language requiring the thermoplastic coating and binding agent to be applied to the medicinal composition as a hot-melt liquid. The 35 U.S.C. 103(a) rejection over Rudkin et al is withdrawn due to the claims limited to a medicinal composition containing a pharmaceutical active substance.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over German Patent No. 4,138,513, Moest, European Patent No. 204,596 and Japanese Patent No. 57-169427.

Nonomura et al and DeHaan et al are withdrawn due to the lack of a recitation of the claimed application of the thermoplastic coating as a hot-melt liquid.

The German and European patents disclose the melt extrusion of a pharmaceutical or biologically active agent or compound coated with Eudragit cationic group-containing acrylic copolymers and fatty acid esters which are suitable pharmaceutical auxiliaries according to column 2, lines 24-28 of Moest. It would have been obvious to prepare the medicinal compositions of Moest and the Japanese patent via the melt extrusion procedure of the German and European patents in order to obtain coated medicinal product with improved storage stability at lower cost.

Any inquiry concerning this communication should be directed to Robert Sellers at telephone number (703) 308-2399 (Fax nos. (703) 305-(5408 or 5433)).

ROBERT E. SELLERS
PRIMARY EXAMINER
GROUP 150

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8/27/97